I. The Office Action

The May 4, 2006 final office action (the "Office Action") in this application:

1.) rejected claims 14, 16, 18, 19, 21, 23 and 25-26 under 35 U.S.C. 112, first paragraph;

2.) rejected claims 14, 16, 18 ,19, 21, 23 and 25-26 under 35 U.S.C. 112, second paragraph;

3.) rejected claims 14, 16, 18 ,19, 21, 23, and 25-26 under 35 U.S.C. 103(a); and

4.) rejected claims 25-26 on the grounds of res judicata.

Applicants petition for a three-month extension of time to reply to the office action. This reply to the final office action is submitted concurrently with a request for continued examination (RCE), hence this response should be entered and the pending claims reconsidered in light of the amendments and remarks submitted below.

Applicants respond as follows.

II. Amendments to claims 14, 19 and cancellation of claims 25-26.

Support for amendments made to the claims can be found in the specification as follows:

Support for the amendment “spasmodic torticollis” in claims 14 and 19 can be found at least at page 5, line 24 and at page 14, line 26 of the specification;

Support for a botulinum toxin type E “that has a spasmodic torticollis alleviation activity of from one to four days” can be found at least in the disclosure of Example 2 on page 14.

Claims 25 and 26 are cancelled without prejudice or disclaimer to further prosecution at a later date.

III. Rejection of claims 14, 16, 18, 19, 21, 23 and 25-26 under 35 U.S.C. 112, first paragraph

The Office Action has rejected claims 14, 16, 18, 19, 21, 23 and 25-26 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Applicants traverse these rejections.

Solely to facilitate prosecution, claims 14, 19 and 25 have been amended to recite the limitation of spasmodic torticollis, support for which can be found at least at page 5, line 24, where the instant specification discloses various neuromuscular disorders or conditions that methods of present invention can treat, as well as page 14, Example 2. As stated in the Office Action on page 3, first paragraph, functional limitations of "substantially alleviated" and "able to hold his head and shoulder in a normal position", are therefore limited to spasmodic torticollis now recited in the claims. Accordingly, claims 14, 16, 18, 19, 21 and 23 do not contain new matter.

Thus, the rejection should be withdrawn.

IV. Rejection of claims 14, 16, 18, 19, 21, 23 and 25-26 under 35 U.S.C. 112, second paragraph

The Office Action has rejected claims 14, 16, 18, 19, 21, 23 and 25-26 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. Applicants respectfully traverse the rejection.

It is noted that relative terms are allowed in patent claims and that "*… the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before*. Placed in that context, it is *unnecessary to spell out every detail* of the invention in the specification;" emphasis ours, (*Falker-Gunter Falkner v. Inglis* (Fed. Cir. 2006, 05–1324) 79 USPQ2d 1001, 1007 (copy attached). Additionally, "substantially" is often used in conjunction with another term to describe a particular characteristic of the claimed invention. *In re Nehrenberg*, 280 F.2d 161, 126 USPQ 383 (CCPA 1960), and the court held that the limitation "which produces substantially equal E and H plane illumination patterns" was definite because one of ordinary skill in the art would know what was meant by "substantially equal." *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988) in M.P.E.P 2173.05(b) (D).

In the instant case one of ordinary skill in the art, such as a physician, having read the instant specification and having knowledge of what has come before, would know what is meant by "substantial alleviation" of the symptoms of spasmodic torticollis. For example and as described in the specification, a person suffering from spasmodic torticollis suffers "stereotyped abnormal devastations of the head, the chin being rotated to one side, and the shoulder being elevated toward the side at which the head is rotated" (see specification at page 14, Example 2). Furthermore, one example of substantial alleviation of symptoms is described as when the patient "is able to hold his head and

shoulder in a normal position" (see specification at pages 14-15, Example 2). One of ordinary skill in the art is clearly able to determine when a person suffering from symptoms of aberrant positioning of their head and shoulder have returned to a normal position. The use of the term "substantially alleviate" as it relates to a symptom of spasmodic torticollis is clearly understood by one of ordinary skill in the art, for if not, physicians treating patient suffering from this malady would not even be able to recognize any progress, or lack thereof, their patients would be making during a prescribed course of treatment.

Thus, the rejection should be withdrawn.

V. Rejection of claims 14, 16, 18, 19, 21, 23, and 25-26 under 35 U.S.C. 103(a)

The Office Action rejected claims 14, 16, 18, 19, 21, 23, and 25-26 under 35 U.S.C. 103(a) as being unpatentable over Ludlow et al. in view of Simpson et al and Janovic et al.

All of the claims are now directed to and recite the limitation of administration of a botulinum toxin type E that has a spasmodic torticollis alleviation activity from one to four days. The administration of such a particular, specific, short acting botulinum neurotoxin, to a patient suffering from spasmodic torticollis and after experiencing a loss of clinical response to the administration of botulinum toxin type A, is not taught or suggested by Ludlow et al. Ludlow et al., in contrast, discloses the use of botulinum toxin type F, which has a relatively long lasting effect on the treatment of torticollis, the shortest time to full return of symptoms being 40 days (see Table on page 349). Contrarily, the present claims are direct to a particular botulinum toxin type E that has a spasmodic torticollis alleviation activity from one to four days.

The Ludlow et al., Simpson et al. and Jankovick et al. references cannot be combined *in the manner claimed* and a prima facie case of obviousness made. Ludlow et al. discloses the use of botulinum toxin type F after antibody formation to botulinum toxin type A is found in patients previously treated with botulinum toxin type A. There is no mention or suggestion in Ludlow et al. to use other types of botulinum toxin types, let alone a botulinum toxin type E having an activity from one to four days, as presently recited in all the claims.

The disclosures of Simpson et al and Jankovick et al., alone or in any combination, fail to remedy this shortcoming. Jankovick et al. throws out the mere germ of the idea of utilizing "other botulinum toxins that are immunologically distinct from type A" (page 1189, right col.) without any suggestion or delineation of parameters to try to arrive at a successful result, and Simpson et al. simply

discloses various botulinum serotypes and does not disclose the specific utilization of a sequential administration of botulinum toxin type A to a patient until the patient experiences a loss of clinical response to the administered botulinum toxin type A, followed by administration of up to 300 units of a botulinum toxin type E that has an activity from one to four days.

Impermissible hindsight reconstruction, support for which cannot even be found in the cited references, is the only manner is which the presently cited references can be combined and the instant claims divined therefrom. Accordingly, the present amended claims are unobvious in light of any combination of Ludlow et al., Simpson et al. and Jankovick et al.

Thus, the rejection should be withdrawn.

VI. Rejection of claims 25-26 on the grounds of res judicata.

The Office Action rejected claims 25-26 of the grounds of res judicata. Applicants' traverse this rejection on the basis that the instant claims are directed to different method of treatment than the claims that were before the Board of Patent Appeals and Interferences in Appeal No. 1997-2367. However and in order to advance prosecution, Applicants have cancelled claims 25 and 26.

Thus, the rejection should be withdrawn.

VII. Conclusion

All issues raised in the Office Action have been addressed. Reconsideration and allowance of claims 14, 16, 18, 19, 21 and 23 is requested.

The Commissioner is hereby authorized to charge any fee(s) required or necessary for the filing, processing or entering of this paper or any of the enclosed papers and to refund any overpayment to deposit account 01-0885.

Respectfully submitted,

/CLAUDE L. NASSIF/

Date: October 12, 2006 Claude L. Nassif, Ph.D., Reg. No. 52,061

Attachment: *Falker-Gunter Falkner v. Inglis* (Fed. Cir. 2006, 05–1324) 79 USPQ2d 1001, 1007

Address all inquires and correspondence to:

Claude L. Nassif, Ph.D.
Allergan, Inc., Legal Department
2525 Dupont Drive
Irvine, CA 92612
Telephone: 714 246 6458
Fax: 714 246 4249